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I. INTRODUCTION

A. Purpose and Summary

The primary purpose of HR 2768 is to create a more collaborative, less confrontational relationship between providers and the Centers for Medicare and Medicaid Services. HR 2768 will diminish the paperwork load required to meet complex and technical regulatory requirements, and allow providers to spend more time with patients. HR 2768 streamlines the regulatory process, enhances education and technical assistance for doctors and other health care providers, and protects the rights of providers in the audit and recovery process to ensure that the repayment process is fair and open.

In addition, HR 2768 gives the Secretary the tools to manage Medicare program operations efficiently. For the first time, the Centers for Medicare and Medicaid Services will be able to competitively contract with the best entities available to process claims, make payments and answer questions. The Secretary will be free to promote quality by creating incentives for the Medicare Administrative Contractors to provide outstanding service to seniors and health care providers. Contractor reform initiatives will eliminate artificial distinctions between Medicare's Part A and Part B with regard to contracting practices. But this does not constitute a combination of the Part A and Part B trust funds or any position on that matter.

Finally, HR 2768 includes several provisions to help beneficiaries interact with and better understand the Medicare program, including the establishment of an internal beneficiary ombudsman program, a demonstration program to place Medicare specialist in Social Security offices, and an improved 800-number to facilitate communication between beneficiaries and CMS or its contractors.

B. Background and Need for the Legislation

HR 2768 was developed through months of consultation with health care providers and other experts, including public hearings before the Ways and Means Subcommittee on Health. Working closely with the Bush Administration, the Subcommittee began a thorough process of evaluation of the regulatory relationship between health care providers and suppliers and the Centers for Medicare and

Medicaid Services (CMS). At the first public hearing that focused on bringing regulatory relief to Medicare providers, held on March 15, 2001,the Subcommittee received testimony from witnesses frustrated with a system that forces health care providers to spend their time and office resources on paperwork rather than patients.

The message delivered by health care providers in that first hearing was unanimous - doctors and hospitals, home health agencies and nursing homes all told the Subcommittee that they are overwhelmed. Instead of caring for patients, health care providers testified that they spend too much time filling out unnecessary and confusing forms.

In addition, Medicare's current contracting represents an antiquated, inefficient, and closed system based on cozy relationships between the government, contractors and providers.

The Medicare contracting program is antiquated because contractors may not service the entire Medicare program, or particular functions within the program; rather Fiscal Intermediaries administer claims for facilities and carriers administer claims for all other providers. It has failed to keep pace with integrated delivery in the private sector.

Medicare's contracting program is inefficient because Medicare does not award contracts through competitive procedures, but rather on provider nomination.

Medicare's contracting program is closed. All but one of the contractors today have been with Medicare since the program's inception 36 years ago, and only insurers can provide contracting services.

C. Legislative History

After the March 15 hearing, Chairman Nancy Johnson and Ranking Member Pete Stark wrote Secretary Thompson with a number of suggestions regarding regulatory improvements the Department could make using existing administrative authority. Many of those changes have already been adopted.

However, because many of the problems identified through the

Subcommittee's work could not be corrected administratively, the Subcommittee began work in March on a legislative package. Through extensive collaboration with the provider community, the General Accounting Office and the Bush Administration, a draft bill was developed. The bill was responsive to issues raised by the Office of Inspector General in order to ensure that the package extends regulatory relief to providers while protecting taxpayers and beneficiaries from waste, fraud, and abuse. The bill was introduced on August 2 as HR 2768 and referred to the Committee on Ways and Means' Subcommittee on Health and the Committee on Energy and Commerce.

On September 25, the Subcommittee held a follow-up hearing on HR 2768 to elicit additional suggestions on the bill as introduced. Testimony was provided by CMS Administrator Tom Scully, the General Accounting Office and representatives of provider groups.

After approving Representative Johnson's amendment in the nature of a substitute, the Subcommittee on Health ordered favorably reported the bill on October 4, 2001 to the full Ways and Means Committee by voice vote with a quorum present with no additional amendments.

On October 11, after approving Chairman Thomas' amendment in the nature of a substitute, the full Committee on Ways and Means ordered favorably reported HR 2768 to the House of Representatives by voice vote with a quorum present . There were no additional amendments.

II. EXPLANATION OF PROVISIONS

Section 1. Short Title; Amendments to Social Security Act; Table of Contents

Current Law. No provision.

Explanation of Provision. Except as otherwise specified, the provisions would amend or repeal a section or other provisions of the Social Security Act. None of the provisions shall be construed to (1) compromise the existing legal authority for addressing Medicare fraud or abuse with respect to criminal prosecution, civil enforcement, or administrative remedies, including those established by the False Claims Act or (2) prevent the Department of Health and Human Services (HHS) from its ongoing efforts to eliminate waste, fraud, and abuse in Medicare. Also, consolidation of Medicare's administrative contracting (as provided for in this bill) would not consolidate the Federal Hospital Insurance Trust Fund, which pays for Part A services, and the Federal Supplementary Medical Insurance Trust Fund, which pays for Part B services. The bill notes that this administrative consolidation does not reflect any position on consolidation of other items related to Part A and Part B. Finally, the term, "supplier," means a physician, practitioner, facility, or other nonprovider entity that furnishes Medicare items or services unless otherwise indicated.

Effective Date. Upon enactment.

Reason for Change. The Subcommittee is committed to extending needed regulatory relief to providers and suppliers while at the same time protecting taxpayers from waste, fraud and abuse.

Section 2. Issuance of Regulations

(a) Consolidation of Promulgation to Once a Month.

Current Law. The Secretary is required to issue regulations that are necessary to administer Parts A and B of the Medicare program. No rule,

requirement or policy statement (other than a national coverage determination) that establishes or changes a substantive legal standard that determines Medicare's scope of benefits, level of payment, or eligibility of individuals, entities or organizations to receive benefits or furnish services can take effect unless it is promulgated by regulation. The Secretary must publish a proposed regulation in the *Federal Register*, with at least 60 days to solicit public comment, before issuing the final regulation with the following exceptions: (1) the statute permits the regulation to be issued in interim final form or provides for a shorter public comment period; (2) the statutory deadline for implementation of a provision is less than 150 days after the date of enactment of the statute containing the provision; (3) under the good cause exception contained in the rule-making provision of Title 5 of the United States Code, notice and public comment procedures are deemed impracticable, unnecessary or contrary to the public interest.

Explanation of Provision. The Secretary would be required (1) to issue proposed or final regulation (including interim final regulation) only on one business day of the month unless publication on another date is necessary to comply with statutory requirements and (2) coordinate the issuance of new regulations relating to a category of provider or supplier based on an analysis of the collective impact of the regulatory changes on such category. No later than 3 years after enactment, the Secretary would be required to report to Congress on the feasibility of issuing regulations only on one day in each calendar quarter.

Effective Date. The provisions would apply to regulations issued 30 days after enactment.

Reason for Change. The volume of Medicare regulations issued by CMS can be difficult for health care providers and suppliers, particularly small providers and suppliers, to monitor. By requiring periodicity on the release of regulations, providers and suppliers will be better able to keep informed of program changes.

The collective impact provision ensures that the Department will consider the overall impact of any changes it is making on categories of providers and suppliers. If the Department determines that many changes affecting a particular category of providers or suppliers are underway, the Department should consult with representatives of that category to determine whether providers and suppliers would be better able to make the systems changes needed to accommodate those changes

if all the new regulations were released simultaneously or staggered. Because of the burden implementing multiple regulations simultaneously can cause, the Secretary needs to coordinate new regulations based on an analysis of the collective impact the regulatory changes will have on any given category of provider or supplier.

(b) Regular Time line for Publication of Final Rules.

Current Law. See above. The Secretary must publish in the *Federal Register* no less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines which are promulgated to carry out Medicare's law.

Explanation of Provision. The Secretary, in consultation with the Director of the Office of Management and Budget, would establish and publish a regular time line for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation. The time line may vary by regulation due to complexity, number and scope of comments received and other factors. The Secretary would be required to publish in the Federal Register any variations in the time line for publication of the final regulation. This notice of the different time line would need to: (1) be published no later than the end of the comment period for the proposed regulation and (2) include a brief explanation of the justification for such variation. If the regular time line established for an interim final regulation expires without promulgation of a final regulation (and associated public comment period), the interim final regulation would not remain in effect unless the Secretary publishes a notice of continuation that would include an explanation for not complying with the regular time line. The interim regulation's regular time line would be restarted on the date that the notice of continuation is published. The Secretary would be required to submit a report to Congress that describes and explains the instances where the final regulation was not published within the applicable time line.

Effective Date. Upon enactment. The Secretary would be required to provide for a transition period for previously published interim final regulations.

Reason for Change. Numerous regulations have been issued by CMS as interim final regulations and never finalized. This injects an element of uncertainty into the regulation in question, and it precludes the ability of CMS to incorporate

changes based on comments received by interested parties into a final regulation. The provision ensures that proposed regulations will move through the process of finalization in a predictable and timely manner.

(c) Limitation on New Matter in Final Regulations.

Current Law. No provision.

Explanation of Provision. A provision in a final regulation that is not a logical outgrowth of the proposed regulation would be treated as a proposed regulation and would not take effect without a separate public comment period followed by publication as a final regulation.

Effective Date. Upon enactment.

Reason for Change. The provision ensures that interested parties will be given an opportunity to comment on issues addressed in regulations before they take effect. The Committee recognizes that proposed regulations for annual payment updates for providers and suppliers include proposed overall payment updates, and that specific payment amounts for specific codes or specific payment areas are not typically included until final rules. The Committee does not intend to change past custom to recognize such details in final rules as a "logical outgrowth" of proposed rules.

Section 3. Compliance with Changes in Regulations and Policies

(a) No Retroactive Application of Substantive Changes; Time line for Compliance with Substantive Changes after Notice.

Current Law. No provision.

Explanation of Provision. A substantive change in Medicare regulations, manual instructions, interpretive rules, policy statements, or guidelines would not be applied retroactively to items or services furnished before the date it was issued, unless the Secretary determines that retroactive application would be necessary to comply with statutory requirements or would have a positive impact on beneficiaries or providers and suppliers. The substantive change would not be effective until at

least 30 days after it is issued. No compliance action could be taken against a provider or supplier with respect to the change for items and services furnished before the effective date.

Effective Date. Upon enactment.

Reason for Change. This provision will ensure providers and suppliers will have sufficient time to make any changes to systems needed to comply with changes in regulations.

(b) Reliance on Guidance

Current Law. No provision.

Explanation of Provision. If (1) a provider or supplier follows written guidance (which may be transmitted electronically) provided by the Secretary or a Medicare contractor when furnishing an item or service and submitting a claim; (2) the Secretary finds that the circumstances relating to the furnished items and services have been accurately presented in writing to the contractor and (3) the guidance is inaccurate, the provider or supplier would not be subject to any sanction including repayment or any penalty. This provision would not be construed to prevent repayment (or payment of penalties) to the extent that the overpayments result from a clerical or technical operational error. GAO is instructed to conduct a study on the feasibility and appropriateness of legally binding advisory opinions on appropriate interpretation and application of Medicare regulations.

Effective Date. Upon enactment.

Reason for Change. This provision will ensure that providers and suppliers who acted in good faith based on the information they received from their contractors will not be vulnerable to recovery if it turns out that the contractor was in error. Providers should be able to rely on the directions or guidance provided to them by their Medicare contractors, even if there is a technical or clerical error on the part of the contractor in developing or providing the direction or guidance. The protections of new section 9(b) are not available in the case of a technical or clerical error that is not incorporated into direction or guidance and therefore not relied upon by the provider in providing supplies or services. For example, a simple

miscalculation in the payment of a claim that results in the wrong amount being sent to a provider would be recoverable.

Section 4. Increased Flexibility in Medicare Administration

(a) Consolidation and Flexibility in Medicare Administration.

Current Law. Section 1816 of the Social Security Act authorizes the Secretary to establish agreements with fiscal intermediaries nominated by different provider associations to make Medicare payments for health care services furnished by institutional providers. Section 1842 of the Act authorizes the Secretary to enter into contracts with health insurer carriers to make Medicare payments to physicians, practitioners and other health care suppliers. Section 1834(a)(12) of the Act authorizes separate regional carriers for the payment of durable medical equipment (DME) claims. Section 1893 authorizes the Secretary to contract for certain program safeguard activities under the Medicare Integrity Program (MIP).

Certain terms and conditions of the contracting agreements for fiscal intermediaries and carriers are specified in the Medicare statute. Medicare regulations coupled with long-standing agency practices have further limited the way that contracts for claims administration services can be established. Specifically, the contracts are awarded without full and open competition; generally must cover the range of claims processing and related activities; cannot be terminated without cause and without the opportunity for a public hearing; and incorporate cost-based, not performance-based, reimbursement methods with no incentive bonuses.

Certain functions and responsibilities of the fiscal intermediaries and carriers are specified in the statute to improve or maintaining good performance as well. The Secretary may not require that carriers or intermediaries match data obtained in its other activities with Medicare data in order to identify beneficiaries who have other insurance coverage as part of the Medicare Secondary Payer (MSP) program. With the exception of prior authorization of DME claims, an entity may not perform activities (or receive related payments) under a claims processing contract to the extent that the activities are carried out pursuant to a MIP contract. Performance standards with respect to the timeliness of reviews, fair hearings, reconsideration and exemption decisions are established as well.

A Medicare contract with an intermediary or carrier may require any of its employees certifying or making payments provide a surety bond to the United States in an amount established by the Secretary. Neither the contractor nor the contractor's employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor's employee who disburses payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon a voucher signed by the certifying employee.

Explanation of Provision. The legislation would add Section 1874A to the Social Security Act which would permit the Secretary to enter into contracts with any entity to serve as a Medicare administrative contractor. These contractors would perform, or secure the performance of (through subcontracting), some or all of the following tasks: determine payment amounts; making payments; educate and assist beneficiaries; consult and communicate with and asistproviders and suppliers; and perform additional functions as necessary. The claims processing jurisdiction of a Medicare administrative contractor would be determined by the scope of the contract awarded to the entity. Specifically, the Medicare administrative contractor that would perform a particular function or activity is the entity that has the contract for that activity for any given beneficiary, any given provider or supplier, or class of provider or supplier.

The Secretary would be required to use competitive procedures when entering into a Medicare administrative contract but would be able to renew a contract for up to five years without regard to statutory requirements concerning competitive contracting if the entity has exceeded specified performance standards. These standards would take into account performance, quality, price, and other factors. Functions would be able to be transferred among Medicare administrative contractors, consistent with these provisions. The Secretary would be required to (1) consider performance quality in such transfers; (2) provide incentives for the Medicare administrative contractors to provide efficient, high-quality services; and (3) develop performance standards with respect to each of the payment, provider service, and beneficiary service functions required of the contractors. With respect to developing the performance standards, the Secretary would be able to consult with providers, suppliers and organizations performing the contracting functions. The Secretary would be required to contract only with those entities that (1) will

perform efficiently and effectively; (2) will meet standards for financial responsibility, legal authority and service quality among other pertinent matters; (3) will agree to furnish timely and necessary data; and (4) will maintain and provide access to necessary records and data. The Secretary retains his authority to cover the termination costs of current contractors.

A Medicare administrative contract would contain provisions deemed necessary by the Secretary and may provide for advances of Medicare funds for the purposes of making payments to providers and suppliers. As under current law, the Secretary would not be able to require existing or new contractors to match their data with Medicare data for the purposes of the identifying beneficiaries with other insurance coverage. The Secretary would assure that the activities of the Medicare administrative contractors do not duplicate the Medicare Integrity Program (MIP) functions except with respect to the prior authorization of DME. An entity with a MIP contract would not be treated as a Medicare administrative contractor, solely by reason of the MIP contract. In developing contract performance requirements for Medicare administrative contractors, the Secretary would be required to consider the inclusion of the existing standards in effect for timeliness of reviews, fair hearings, reconsideration and exemption decisions.

A Medicare administrative contractor and any of its employees certifying or disbursing payments may be required to provide a surety bond to the United States in an amount established by the Secretary. It is the intent of Congress that the definition of a surety bond in this instance includes fidelity bonds and the Secretary has the authority to request fidelity bonds. The liability standard of "gross negligence or intent to defraud" is retained for individuals and designated officers but the agency and organization are now also liable under a "gross negligence or intent to defraud" standard; neither the contractor nor the contractor's employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor's employee who disburses payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon an authorization from the certifying employee AND the authorization meets the internal control standards established by General Accounting Office (GAO). The Secretary would pay the Medicare administrative contractor, its employees, or their legal representatives for defending these contractors or employees in a civil action related to the performance of their

contractual duties, if due care was exercised in the performance of such duties. These payments would be equal to the reasonable amount of legal expense incurred.

Effective Date. See subsection (d).

Reason for Change. Medicare's current contracting represents an antiquated, inefficient, and closed system based on cozy relationships between the government, contractors and providers.

- The Medicare contracting program is antiquated because contractors may not provide service for the entire Medicare program, or particular functions within the program; rather Fiscal Intermediaries administer claims for facilities and carriers administer claims for all other providers. It has failed to keep pace with integrated claims administration practices in the private sector.

- Medicare's contracting program is inefficient because Medicare does not award contracts through competitive procedures, but rather on provider nomination.

- Medicare's contracting program is closed. All but one of the contractors today have been with Medicare since the program's inception 36 years ago, and only insurers can provide contracting services.

This provision permits greater flexibility in contracting for administrative services between the Secretary and the Medicare contractors (entities that process claims under part A and part B of the Medicare program), including the flexibility to separately contract for all or parts of the contractor functions. The Secretary also may contract with a wider range of entities, so that the most efficient and effective contractor can be selected.

These amendments require the Secretary to contract competitively at least once every five years for the administration of benefits under parts A and B. In conjunction with the elimination of cost contracts, it is intended to create incentives for improved service to beneficiaries and to providers of services and suppliers. Finally, it establishes a liability standard of gross negligence or intent to defraud for

the agency or organization, to eliminate a statutory ambiguity that appeared to extend immunity to that entity for fraudulent payments certified and disbursed to Medicare Part A providers.

(b) Conforming Amendments to Section 1816 (Relating to Fiscal Intermediaries).

Current Law. Section 1816 of the Social Security Act establishes the provider nomination process, the contracting specifications, and performance standards for fiscal intermediaries that currently contract with Medicare to process claims and perform other related administrative activities for institutional providers.

Explanation of Provision. The provisions establish that the activities of fiscal intermediaries in administering Medicare would be conducted through contracts with Medicare administrative contractors as set forth in subsection (a). The provider nomination process and contracting specifications would be repealed. Certain performance standards with respect to the processing of clean claims would be retained. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

Effective Date. See subsection (d).

Reason for Change. These amendments provide a basis for a unified contracting system for the administration of parts A and B, identical to the recent Congressionally mandated structure of the Medicare Integrity Program contractors. Consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the elimination of provider nomination, which has been rarely allowed in recent years, is essential for bringing full and open competition into the contracting functions of the Medicare program.

(c) Conforming Amendments to Section 1842 (Relating to Carriers).

Current Law. Section 1842 of the Social Security Act establishes that carriers will be used to administer certain Medicare benefits as well as the contracting requirements and certain performance standards for those activities.

Explanation of Provision. The provisions would establish that the activities of carriers administering Medicare would be conducted through contracts with Medicare administrative contractors as set forth in subsection (a). Certain instructions including those pertaining to nursing facilities' payments, claims assignment, physician participation, overpayment recoveries and billing by suppliers would be retained. Certain performance standards with respect to the processing of clean claims would be retained. Contracting specifications and other conforming changes would be established. The Secretary, not the contractor, would be responsible for taking necessary actions to assure that reasonable payments are made, for those made on both cost and charge basis. The Secretary, not the contractor, would be responsible for maintaining a toll-free telephone number for beneficiaries to obtain information on participating suppliers. Carrier fair hearing requirements would be eliminated. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

Effective Date. See subsection (d).

Reason for Change. The provision establishes a basis for a unified contracting system, identical to the structure implemented for the Medicare Integrity Program contractors. It is important to note, however, that consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the Secretary would have the flexibility to choose the best contractor(s) to provide telephone information on suppliers which is intended to reduce administrative costs and improve quality.

(d) Effective Date; Transition Rule.

Current Law. No provision.

Explanation of Provision. Except as otherwise provided in this subsection, the provisions in this section would be effective October 1, 2003. The Secretary would be authorized to take necessary actions prior to that date in order to implement these amendments on a timely basis to transition from the contracts established under sections 1816 and 1842 of the Social Security Act to those established under the new section 1874A created by this legislation. The transition would be consistent with the requirement that the administrative contracts be

competitively bid by October 1, 2008. The requirement that MIP contracts be awarded on a competitive basis would continue to apply and would not be affected by the provisions in this section. The MIP contracting exception that allows agreements according to current law would be deemed to be a contract established under the new authority of 1874A and would continue existing activities. The Secretary has the authority to recognize the appropriate termination costs of current cost contracts in the transition from current cost contracts to competitively bid contracts.

Reason for Change. The provision provides for the appropriate transition between the current contracting system and these amendments.

(e) References

Current Law. No provision.

Explanation of Provision. After this section becomes effective, any reference to fiscal intermediary or carrier would be considered a reference to the appropriate Medicare administrative contractor.

Reason for Change. These amendments are necessary to conform existing law to the new structure.

Section 5. Provider Education and Technical Assistance.

(a) Coordination of Education Funding.

Current Law. Medicare's provider education activities are funded through the program management appropriation and through the Education and Training component of the Medicare Integrity Program (MIP). Both claims processing contractors (fiscal intermediaries and carriers) and MIP contractors may undertake provider education activities.

Explanation of Provision. The provision would add Section 1889 to the Social Security Act which would require the Secretary to (1) coordinate the educational activities provided through the Medicare administrative and MIP contractors and (2) to submit an evaluation to Congress on actions taken to

coordinate the funding of provider education.

Effective Date. Upon enactment with report due to Congress no later than October 1, 2002.

Reason for Change. This provision is intended to ensure that federal spending on provider education is coordinated and used as efficiently as possible to maximize the value obtained from the investment. It is not intended to change the proportion or Medicare Integrity Program funds spent on provider education.

(b) Incentives to Improve Contractor Performance.

Current Law. No specific statutory provision. Since FY1996, as part of the audit required by the Chief Financial Officers Act, an estimate of improper payments in Medicare fee-for-service has been established annually. As a recent initiative, CMS is implementing a comprehensive error rate testing program to produce national, contractor specific, benefit category specific and provider specific paid claim error rates.

Explanation of Provision. The Secretary would be required to (1) develop a methodology, in consultation with representatives of providers and suppliers, to measure the specific claims payment error rates at each Medicare administrative contractor; and (2) identify best practices developed at each contractor for educating providers and suppliers. The Secretary would be required to report to Congress on (1) the use of the claims error rate methodology in assessing the effectiveness of contractors' provider education and outreach programs and (2) whether methodology should be used as the basis of bonuses for contractors. The report shall also include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

Effective Date. Methodology is to be implemented and report is due to Congress by October 1, 2003.

Reason for Change. This provision would ensure that the Department monitors contractor level performance as it relates to claims payment error rates, and it would identify best practices for provider education - all with the goal of

reducing payment errors and helping providers and suppliers better comply with program requirements.

(c) Provision of Access to and Prompt Responses from Medicare Administrative Contractors.

Current Law. No specific statutory provision. Statutory provisions generally instruct carriers to assist providers and others who furnish services in developing procedures relating to utilization practices and to serve as a channel of communication relating information on program administration. Fiscal intermediaries are generally instructed to (1) provide consultative services to institutions and other agencies to enable them to establish and maintain fiscal records necessary for program participation and payment and (2) serve as a center for any information as well as a channel for communication with providers.

Explanation of Provision. Each Medicare administrative contractor would be required to (1) respond clearly, concisely and accurately to billing and cost reporting questions; (2) maintain a toll-free telephone number for such inquiries; (3) maintain a system for identifying, and disclosing on request, which employee provided the information; and (4) monitor the quality of the information provided. The Secretary would be required, in consultation with provider organizations, to establish performance standards with respect to telephone inquiries from providers and suppliers.

Effective Date. October 1, 2003.

Reason for Change. This provision is intended to improve contractor accountability to make contractors more responsive to providers and suppliers, and to increase the accuracy and reliability of the information provided in response to the questions received.

(d) Improved Provider Education and Training.

Current Law. In FY2000, $54.8 million was spent on provider education and training activities: about $43 million from the program management appropriation and about $12 million came from the Provider Education and Training component of MIP. In FY2001, about $57.3 million was budgeted for these activities.

Explanation of Provision. The provision would authorize an increased $10 million appropriation from Medicare Trust Funds (as appropriate from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) in FY2003 and FY2004 to increase Medicare contractors' billing, coding and other provider training activities. Medicare administrative contractors would be required to conduct education and training activities for small providers of services or suppliers, that is, institutional providers with less than 25 full-time equivalents (FTEs) or suppliers with less than 10 FTEs.

Effective Date. October 1, 2002.

Reason for Change. This provision acknowledges that contractors are being instructed to significantly improve their provider education and training efforts, and accordingly authorizes new funds to be available for those purposes.

(e) Requirement to Maintain Internet Sites.

Current Law. No provision.

Explanation of Provision. The Secretary and each Medicare administrative contractor would be required to maintain an Internet site which provides easily accessible answers to frequently asked questions as well as other published materials of the contractor.

Effective Date. October 1, 2002.

Reason for Change. This provision will facilitate greater ease of provider and supplier access to information provided by Medicare's contractors.

(f) Additional Provider Education Provisions.

Current Law. No provision.

Explanation of Provision. A Medicare contractor would not be able to use attendance records at educational programs or information gathered during these programs to select or track providers or suppliers for audit or prepayment review. Nothing in the proposed legislation would require Medicare administrative

contractors to disclose claims processing screens (computer edits that trigger medical review) or information that would compromise pending law enforcement activities or law enforcement-related audits.

Effective Date. Upon enactment.

Reason for Change. This provision addresses a concern raised by providers and suppliers that their participation in educational forums has been used to trigger audits. Participation in educational forums should be encouraged not discouraged.

Section 6. Small Provider Technical Assistance Demonstration Program.

Current Law. No provision.

Explanation of Provision. The Secretary would be required to establish a demonstration program that offers technical assistance, upon request, to small providers or suppliers (institutional providers with less than 25 full-time equivalents (FTEs) or suppliers with less than 10 FTEs.) Technical assistance would include direct in-person examination of billing systems and internal controls by qualified entities, such as peer review organizations or other entities. The technical assistance would also make available information and assistance regarding policies and procedures under Medicare, including coding and reimbursement. In awarding these contracts, the Secretary would be required to consider any prior investigations of the entity's work by the Office of the Inspector General (OIG) in HHS or the GAO. Participating providers and suppliers would be required to pay an amount estimated and disclosed in advance that would equal 25% of the cost of the technical assistance they received. Absent indications of fraud, errors found in the review would not be subject to recovery if the problem is corrected within 30 days of the on-site visit and remains corrected for an appropriate period. GAO, in consultation with the OIG, would be required to evaluate and recommend continuation of the demonstration project no later than two years after its implementation. The evaluation would include a determination of whether claims error rates were reduced for providers and suppliers who participated in the program. The evaluation would also study whether improper payments were made as a result of the demonstration. The provision would authorize $1 million in FY2003 and $6 million in FY2004 of appropriations from the Medicare Trust Funds to carry out demonstration project.

Effective Date. Upon enactment.

Reason for Change. Many large providers and suppliers have contracts with private consulting firms to help them navigate their interactions with the Medicare program. This type of assistance can be prohibitively expensive for small providers and suppliers - but they too are required to comply with complex program rules and regulations. This provision creates a new demonstration program to facilitate small provider and supplier access to expert technical assistance. The demonstration will also test whether encouraging technical assistance on the front end to help providers and suppliers play by the rules can save the program money in the longer term by promoting greater program compliance.

Section 7. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman.

Current Law. No statutory provisions address Medicare Provider or Beneficiary Ombudsman programs. The Secretary is required to prepare and distribute an annual notice explaining Medicare benefits and limitations to coverage to Medicare beneficiaries. The Secretary is also required to provide information via a toll-free telephone number.

Explanation of Provision. The Secretary would be required to appoint a Medicare Provider Ombudsman to (1) to resolve unclear guidance and provide confidential assistance to providers and suppliers regarding complaints or questions about the Medicare program, including peer review and administrative requirements; and (2) recommend changes to improve program administration.

The Secretary would also be required to appoint an internal Medicare Beneficiary Ombudsman from individuals with health care expertise and advocacy. The ombudsman would (1) receive complaints, grievances, and requests for information from Medicare beneficiaries; (2) provide assistance with respect to those complaints, grievances and requests, including assistance to beneficiaries who appeal claims determinations or those affected by the decisions of Medicare+Choice organizations to leave Medicare; and (3) submit an annual report to Congress and the Secretary describing activities and recommending changes to improve program administration from a beneficiary perspective.

The provision would authorize appropriations of necessary sums in FY2002 and subsequently from the appropriate Medicare Trust Funds for these Ombudsman programs.

Finally, the Secretary would be required to establish a toll-free number (1-800-MEDICARE) to triage individuals with questions or seeking help to the appropriate individuals or entities. The triage would occur with no charge. This toll-free number would be the only general information and assistance number listed in the Medicare handbook and annual notice provided to Medicare beneficiaries, replacing phone numbers for Medicare contractors. However, assistance numbers that are not Medicare contractors would continue to be listed separately, such as numbers for State Health Insurance Counseling and Assistance Programs.

Effective Date. Upon enactment.

Reason for Change. Beneficiaries and providers are currently confronted with a morass of bureaucracy and regulation, with no clear individual to assist them. The beneficiary handbook currently provides many pages of phone numbers, which can be very confusing for beneficiaries, rather than a single number that then triage beneficiaries to the appropriate person or entity. The provisions in this section are intended to help providers and beneficiaries navigate Medicare's complicated rules and regulations.

Section 8. Provider Appeals.

(a) Medicare Administrative Law Judges.

Current Law. Medicare beneficiaries and, in certain circumstances, providers and suppliers of health care services, may appeal claims that are denied or payments that are reduced. Section 1869 of the Social Security Act was amended by Benefits Improvement and Protection Act of 2000 (BIPA) in its entirety, but the BIPA provisions are not yet effective. Generally, parties who have been denied coverage of an item or service have the right to appeal that decision through a series of administrative appeals and then into federal district court if the amounts of disputed claims in question meet certain thresholds at each step of the appeals process. A hearing by an administrative law judge (ALJ) in the Social Security Administration (SSA) is one component of the administrative appeals process.

Explanation of Provision. By October 1, 2003, the Commissioner of SSA and the Secretary would be required to develop and implement a plan to transfer the functions of the ALJs responsible for hearing Medicare cases from SSA to Health and Human Services. This plan would include recommendations on the number of judges and support staff required to adjudicate cases on a timely basis and funding needed for FY2004 and subsequently. The Secretary of HHS is required to submit to the Committee on Ways and Means of the House of Representatives, the Committee on Finance of the Senate, and the Comptroller General the terms of the plan by July 1, 2003. By September 1 of that year, GAO has to report back to the Committees with an evaluation of the transfer plan. The provision would authorize increased appropriations, in addition to amounts otherwise appropriated, from the appropriate Medicare Trust Fund of $5 million in FY2003 and as necessary in subsequent years in order to increase the number of administrative law judges and to improve education and training programs for judges and their staff in carrying out their Medicare activities. Nothing in this provision would be construed to affect the independence of ALJs in carrying out their responsibilities for adjudicating cases.

Effective Date. Upon enactment, with the mandated report concerning ALJ transfer due by October 1, 2003.

Reason for Change. The Office of Inspector General has identified moving the functions of the Medicare Administrative Law Judges to the Department of Health and Human Services as an important priority in improving the appeals system. This provision makes that transition and increases the emphasis on providing training Administrative Law Judges and their staffs to increase their expertise in Medicare's rules and regulations. The SSA Commissioner and the Secretary are instructed to work together on the transition plans in order to assure that the transition does not adversely affect the SSA ALJ appeals system.

(b) Process for Expedited Access to Judicial Review.

Current Law. Section 1869 (as modified by BIPA but not yet implemented) provides for expedited proceedings. Under BIPA provisions, an expedited determination is available to a beneficiary who has received notice: (1) that a provider plans to terminate services and a physician certifies that failure to continue services is likely to place the beneficiary's health at risk; or (2) the provider plans to discharge the beneficiary. In instances where the moving party alleges that no

material issues of fact are in dispute, the Secretary will make an expedited determination as to whether any such facts are in dispute and, if not, will render a decision expeditiously.

Explanation of Provision. The Secretary would be required to establish a process where a provider or supplier of a service or a beneficiary who has filed an appeal may obtain access to judicial review when a *review panel* determines, no later than 60 days after the date of the written request and submission of supporting documentation, that it does not have the authority over law or regulation in question and where material facts are not in dispute. If so decided, the appellant would be able to bring a civil court action if the civil action is filed within 60 days. The venue for judicial review would be the U.S. District Court where the appellant is located, or where the greatest number of appellants are located, or in the district court in DC. The amount in controversy would be subject to annual interest awarded to the prevailing party by the reviewing court. The provision for expedited access to judicial review would apply to a provider's appeal concerning program participation.

A review panel would be an administrative law judge (ALJ), the Departmental Appeals Board (DAB), a Qualified Independent Contractor (QIC) or other designated entity. A decision by the review panel would be a final decision and would not be subject to review by the Secretary. The appellant would be able to request this determination only once with respect to a particular question of law or regulation.

These expedited access to judicial review provisions will also apply to application of termination proceedings, relating to survey and certification determinations, under 1866(h).

Effective Date. Applies to appeals filed on or after October 1, 2002.

Reason for Change. This provision ensures that if a review board certifies that there are no material facts in dispute and that the appeals process does not have authority to resolve the question at issue, the provider, supplier, or beneficiary may take their case to court in an expedited manner. This will facilitate more prompt resolution of challenges to the underlying validity of CMS regulations and determinations.

(c) Requiring Full and Early Presentation of Evidence.

Current Law. No provision.

Explanation of Provision. A provider of services or supplier would not be able to introduce evidence that was not presented at reconsideration conducted by the QIC unless a good cause precluded its introduction at or before that reconsideration.

Effective Date. On or before October 1, 2002.

Reason for Change. The Office of Inspector General identified this change as a priority to promote more expeditious resolution of appeals of denied claims. This provision requires prompt introduction of evidence relevant to a provider appeal.

Section 9. Recovery of Overpayments and Prepayment Review; Enrollment of Providers.

(a) Recovery of Overpayments and Prepayment Review.

Current Law. No specific statutory provisions address the payment plans, consent settlements, prepayment, or post-payment actions. Section 1833(j) of the Social Security Act provides that interest accrues on under-payments or overpayments starting 30 days of the date of the final determination of the accurate payment amount.

Explanation of Provision. Subject to certain qualifications, in circumstances where refund of an overpayment within 30 days would constitute a hardship, providers and suppliers would be allowed to repay overpayment amounts over a period of up to three years when their overpayment obligation exceeds a 10% threshold of their annual payments from Medicare. The Secretary would be able to determine cases of extreme hardship where a repayment period of up to five years could be established. Interest would accrue on the balance through the repayment period. The Secretary would be required to establish the way that newly-participating providers and suppliers could qualify for a repayment plan under this hardship provision. Previous overpayment amounts already included in an ongoing

repayment plans would not be included in the calculation of the hardship threshold. The Secretary would be allowed to seek immediate collection if payments are not made as scheduled. Exceptions to this provision would be permitted in cases where bankruptcy may be declared or fraud or abuse is suspected.

For providers and suppliers who appeal an overpayment determination, the Secretary would be prevented from recovering an overpayment until the date of the qualified independent contractor decision. The Secretary would be required (1) to collect interest that accrues starting on the date of the overpayment notice if the appeal decision is against the provider, physician, practitioner or supplier and (2) to pay the recouped amount plus interest if the appeal decision is subsequently reversed.

Medicare contractors, both MIP and Medicare administrative contractors, would be able to conduct random prepayment reviews only in order to develop contractor-wide or program-wide claims payment error rates. These random prepayment reviews would be developed in consultation with providers and suppliers. Contractors would be able to deny payments for claims subject to the prepayment reviews.

Medicare contractors would not be able to use extrapolation to determine overpayment amounts unless a sustained or high level of payment error exists (as defined by the Secretary through regulations) or a documented educational intervention did not correct the payment error.

Medicare contractors would be permitted to periodically request records or documentation for a limited sample of claims from providers or suppliers who had been overpaid to ensure that the previous practices have been corrected.

The Secretary would be able to use a consent settlement to resolve a projected overpayment. As part of the process, the Secretary would be required to (1) communicate in a non-threatening manner to a provider, or supplier that, based on a preliminary analysis of medical records, an overpayment may exist; (2) provide 45days where additional information may be submitted by the provider and supplier regarding these medical records; (3) after considering the additional information, provide notice and explanation of any remaining overpayment determination; and (4) offer the opportunity for a statistically valid random sample (which would not

waive appeal rights) or a consent settlement (based on a smaller sample with a waiver of appeal rights) to resolve the overpayment amounts.

Medicare contractors would not be able to implement non-random prepayment review based on initial identification of an improper billing practice by the provider or supplier unless a sustained or high level of payment error exists. The Secretary would be required to issue regulations concerning the timing and termination of prepayment reviews as well as the different circumstances that would affect the duration of these reviews.

Medicare contractors would be required to provide a written notice of the intent to conduct a post-payment audit to providers, and suppliers selected as audit candidates. During the exit conference between the provider or supplier and the contractor, the contractor would be required to provide a full review and understandable explanation of the findings to those who have been audited. This full review (1) would permit the development of an appropriate corrective action plan; (2) would provide information on appeal rights; (3) would provide for an opportunity to supply additional information to the contractor; and (4) take into account that additional information which was provided on a timely basis. A notice of audit or explanation of findings would not be required if law enforcement activities or audits would be compromised.

The Secretary would be required to establish a process where classes of providers and suppliers are notified that their Medicare contractor has identified specific billing codes that may be over-utilized.

Effective Date. Upon enactment.

Reason for Change. These provisions build greater consistency and predictability into Medicare's rules for recovery of overpayments and prepayment review, while protecting program integrity.

(b) Enrollment Process for Providers of Services and Suppliers.

Current Law. Providers and, to some extent, suppliers have access to certain appeal mechanisms if their application to participate in Medicare is denied or terminated. Section 1866(h) of the Social Security Act provides for a hearing and

for judicial review of that hearing for any institution or agency dissatisfied with a determination that it is not a provider (or that it can no longer be a provider). There is no statutory provision extending such judicial appeal rights to suppliers. Sections 1128(a) and (b) of the Act provide for the exclusion of certain individuals or entities because of the conviction of crimes related to their participation in Medicare; Section 1128(f) provides for hearing and judicial review for exclusions. In 1999, the Health Care Financing Administration (HCFA–now the Centers for Medicare and Medicaid Services or CMS) published a proposed regulation that would revise existing Medicare Part B administrative appeals procedures and extend them to all suppliers not currently covered.

Explanation of Provision. The Secretary would be required to establish by regulation an enrollment process which provides an appeal mechanism with prompt deadlines for those providers and suppliers whose applications to participate in Medicare are denied.

Effective Date. Within 6 months of enactment.

Reason for Change. This provision gives providers and suppliers an opportunity to appeal denials of their applications to participate in the Medicare program.

(c) Process for Correction of Minor Errors and Omissions on Claims Without Pursuing Appeals Process.

Current Law. No provision.

Explanation of Provision. The Secretary would be required to develop, in consultation with appropriate Medicare contractors and health care associations, a process where minor claims errors can be corrected and resubmitted without appealing the claims denial.

Effective Date. Upon enactment.

Reason for Change. Many of the providers and suppliers who testified before the Subcommittee or contacted members directly emphasized the need to

create a process in which they could correct claims that were denied because they were incomplete or contained minor errors without having to pursue a formal appeal. This provision instructs the Secretary to create such a process, which will alleviate pressure on the appeals system. The Subcommittee would be concerned, however, if this process were to become an incentive for providers to knowingly or negligently submit incomplete information.

The Committee intends that the process for correction of minor errors and omissions on claims cover both the submission of prepayment and post-payment review claims. For example, if in the case of a home health claim, the physician has signed the plan of care and/or physician's order but has not dated it, the claim shall be returned to the home health agency and may be resubmitted by the home health agency with any incomplete or missing information without having to appeal the claim.

Section 10. Beneficiary Outreach Demonstration Program.

Current Law. No provision.

Explanation of Provision. The Secretary would be required to establish a 3-year demonstration project where Medicare specialists who are HHS employees are placed in at least six SSA offices to advise and assist Medicare beneficiaries. The SSA offices would be those with a high-volume of visits by Medicare beneficiaries; at least two of the offices wold be in rural areas. In the rural SSA offices, the Secretary would provide for the Medicare specialists to travel among local offices on a scheduled basis. The Secretary would be required to (1) evaluate the project with respect to beneficiary utilization, beneficiary satisfaction, and cost-effectiveness and (2) recommend whether the demonstration should be established on a permanent basis.

Effective Date. Upon enactment.

Reason for Change. This provision makes Medicare experts available in six Social Security Administration offices to assist beneficiaries and answer their questions. The demonstration will test whether such outsourced Medicare specialists improve beneficiary utilization and understanding of the program, and

beneficiary satisfaction.

Section 11. Policy Development Regarding Evaluation and Management (E& M) Documentation Guidelines.

Current Law. No provision.

Explanation of Provision. The Secretary would not be permitted to implement any documentation guidelines for evaluation and management (E&M) physician services unless the guidelines (1) are developed in collaboration with practicing physicians after assessment by the physician community; (2) based on a plan with deadlines for improving use of E&M codes; (3) are developed after completion of the pilot projects to test modifications to the codes; (4) are found to meet the desired objectives; and (5) are preceded by appropriate outreach and education of the physician community. The Secretary would make changes to existing E&M guidelines to reduce paperwork burdens on physicians. The Secretary would be required to modify E&M guidelines to (1) enhance clinically relevant documentation: (2) decrease the non-clinically pertinent documentation; (3) increase the reviewers' accuracy; and (4) educate the physicians and the reviewers.

The provisions would establish different pilot projects in specified settings that would be (1) conducted in consultation with practicing physicians; (2) be of sufficient length to educate physicians and contractors on E&M guidelines and (3) allow for an assessment of E&M guidelines and their use. A range of different projects would be established, including a peer review method by physicians as well as projects in a rural area, outside rural areas as well as in a teaching setting and non-teaching setting. One of the pilot programs would focus on an alternative method to detailed guidelines, based on physician documentation of face to face encounter time with a patient. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Data collected under these projects would not be the basis for overpayment demands or post-payment audits. The Secretary, in consultation with practicing physicians, would be required to evaluate the development of alternative E&M documentation systems with respect to administrative simplification requirements and report results of the study to Congress. The Medicare Payment Advisory Commission would conduct an analysis of the results of this study and submit a report to Congress.

The Secretary would be required to conduct a study of the appropriate coding of extended office visits where no diagnosis is made and submit a report with recommendations to Congress.

Effective Date. Upon enactment.

Reason for Change. This provision is designed to promote greater consultation with practicing physicians with regard to the complicated evaluation and management and coding requirements governing Medicare payment for physician services.

Section 12. Improvement in Oversight of Technology and Coverage.

(a) Improved Coordination Between FDA and CMS on Coverage of Breakthrough Medical Devices.

Current Law. No provision.

Explanation of Provision. At the request of the applicant and to the extent feasible and upon request, the Secretary would be required to coordinate and share appropriate information under reviews of Medicare coverage decisions and Food and Drug Administration's (FDA) reviews of applications for pre-market approval of class III medical devices under Section 515 of the Federal Food, Drug, and Cosmetic Act. The Secretary would be required to submit a report on the implementation plan to lessen the delay between FDA's pre-market approval and Medicare's coding and coverage decisions to the appropriate Congressional committees. This provision would not change Medicare's coverage nor FDA's pre-market approval criteria.

Effective Date. Upon enactment with report to Congress on implementation plan due no later than six months after enactment.

Reason for Change. After the FDA pre-market approval, the Medicare program does a second evaluation of breakthrough technologies to determine effectiveness and cost of those technologies compared to existing technologies. The review is necessary and appropriate, but it can take months between FDA approval and the availability of new technology for Medicare beneficiaries. By coordinating

FDA and CMS approval of breakthrough medical devices, where feasible, this provision is intended to facilitate a more efficient process for the coverage of certain new technology by the Medicare program.

(b) Council for Technology and Innovation.

Current Law. No provision.

Explanation of Provision. The Secretary is required to establish a Council for Technology and Innovation within the Centers for Medicare and Medicaid Services (CMS) and appoint or designate a Executive Coordinator for Technology and Innovation. The Council would be composed of senior CMS staff chaired by the Executive Coordinator who reports to the CMS administrator. The Council shall coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

Effective Date. Upon enactment.

Reason for Change. CMS personnel responsible for coverage, coding and payment of medical innovation are often not well coordinated. This provision creates a focal point for technology and innovation within the Centers for Medicare and Medicaid Services by creating a Council to coordinate across the different Centers and Offices with responsibilities in this area. The Executive Coordinator also provides a single point of contact for outside groups, similar to recent initiatives launched by the Secretary for specific issues and types of providers.

(c) GAO Study on Improvements in External Data Collection for Use in the Medicare Inpatient Payment System.

Current Law. No provision.

Explanation of Provision. GAO would be required to conduct a study which analyzes how external data can be collected for use in computing Medicare's inpatient hospital payments. The study may include an evaluation of the feasibility and appropriateness of using quarterly samples or special surveys among other

methods. The study would include an analysis of whether other agencies, such as the Bureau of Labor Statistics in the Department of Commerce, are best suited to collect this information.

Effective Date. Report is due no later than October 1, 2002.

(d) Application of OSHA Blood borne Pathogens Standards to Certain Hospitals.

Current Law. No provision.

Explanation of Provision. Public hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 would be required to comply with the Blood Borne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations. A hospital that fails to comply with the requirement would be subject to a civil monetary penalty, but would not be terminated from participating in Medicare.

Effective Date. Applies to hospitals as of July 1, 2002.

Reason for Change. Last year, Congress enacted legislation that requires hospitals to utilize safe needles. However, that legislation only applies to non-government hospitals. Twenty-four states have similar requirements on public hospitals. This provision would protect the health and safety of health care workers in those facilities by requiring public hospitals in the other 26 states and the District of Columbia to comply with this important standard.

(e) IOM Study on Local Coverage Determinations.

Current Law. No provision.

Explanation of Provision. The Secretary would be required to arrange for a study by the Institute of Medicine (IOM) that would examine the capabilities and information available to establish Medicare's local coverage determinations. The study would examine: (1) the consistency of definitions used in the determinations; (2) the extent to which the determinations are based on evidence; (3) the advantages and disadvantages of local decision making; (4) whether, in the absence

of adequate data, determinations to cover experimental items or services are made in order to collect data; (5) the advantages and disadvantages of maintaining local medicare contractor advisory committees.

Effective Date. The IOM study would be due to the Secretary no later than three years after enactment when it would be promptly transmitted to Congress.

(f) Methods for Determining Payment Basis For New Lab Tests.

Current Law. No provision.

Explanation of Provision. The Secretary would be required to establish by regulation procedures for determining the basis for any new clinical diagnostic laboratory test. The Secretary must make information available to the public on the methodology and data.

Effective Date. January 1, 2003.

Reason for Change. The Secretary of Health and Human Services is required to establish by regulation an open process for any clinical diagnostic laboratory test. Under the regulations, the Secretary shall develop criteria for use in determining whether a laboratory test should be established through gap-filling or cross-walking to an existing code. When existing services are not sufficient and gap filling must be used, the criteria shall explain the basis of the data, the collection of the data, and the methodology for computing the rate.

The intent of Congress is to open the process to allow CMS to have access to information from beneficiaries, physicians, health care experts and laboratories. Using the information it receives through this new process, CMS shall develop and make available to the public the information used to arrive at a final determination. The information will include the rationale for each such determination, the data on which the determination is based, and responses to public comments.

Section 13. Miscellaneous Provisions.

(a) Treatment of Hospitals for Certain Services Under the Medicare Secondary Payor (MSP) Provisions.

Current Law. In certain instances when a beneficiary has other insurance coverage, Medicare becomes the secondary insurance. Medicare Secondary Payor is the Medicare program's process for coordination of benefits with other insurers. Section 1862(b)(6) of the Social Security Act requires an entity furnishing a Part B service to obtain information from the beneficiary on whether other insurance coverage is available.

Explanation of Provision. The Secretary would not require a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payor provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services would be those clinical laboratory diagnostic tests and interpretations of same that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

Effective Date. Upon enactment.

Reason for Change. Hospitals would not have to directly contact each beneficiary on their retirement date, black lung status and other insurance information for reference laboratory services. While current law provisions for a claim containing valid insurance information are maintained, this provision is intended to reduce the amount of paperwork and regulatory burden related to the provision of these reference laboratory services by hospital-based entities.

(b) Clarification of Prudent Layperson Test for Emergency Services Under the Medicare Fee-for-Service Program.

Current Law. Medicare requires participating hospitals that operate an emergency room to provide necessary screening and stabilization services to a patient in order to determine whether an emergency medical situation exist prior to asking about insurance status of the patient.

Explanation of Provision. Services that are provided by a hospital or a critical access hospital to a Medicare beneficiary who is not enrolled in Medicare +Choice plans in order to evaluate or stabilize an emergency medical condition that meets the application of the prudent layperson rule are deemed to be reasonable and

necessary covered services.

Effective Date. Effective for items or services furnished on or after January 1, 2002.

Reason for Change. This change is intended to clarify that services provided by hospitals under the Federal mandate on the provision of emergency services to assure the health and safety of Medicare beneficiaries are covered by the Medicare fee-for-service program. It will eliminate regulatory burden by eliminating the necessity for the hospital to provide additional documentation or to appeal the denial of services provided under the prudent layperson standard. It is not intended to eliminate the section flexibility in a broader policy.

(c) Submission of Overdue Reports on Payment and Utilization of Outpatient Therapy Services

Current Law. Congress required the Secretary to submit a report by January 1, 2001 on the establishment of a mechanism for assuring appropriate utilization of outpatient therapy services. The Secretary was also required to conduct a study on the utilization of therapy services by June 30, 2001.

Explanation of Provision. The moratoria delaying annual outpatient therapy caps imposed by the Balanced Budget Act of 1997 will expire on October 1, 2002. The Committee believes that the reimbursement policy for outpatient therapy services should be based on a policy that is not arbitrary but protects the program from the provision of inappropriate services. The Secretary is urged to submit the required reports to Congress immediately so that Congress can review any alternative policies on this issue as soon as possible.

Effective Date. Upon enactment.

(d) Authorizing Use of Arrangements with Other Hospice Programs to Provide Core Hospice Services in Certain Circumstances

Current Law. Hospice programs are not permitted to use services provided under arrangement rather to deliver hospice services. Services provided under arrangement are permitted for Part A and Part B hospital services as well as skilled

nursing services. However, the originating hospital or skilled nursing facility is required to bill for the service and be responsible for the quality of care delivered by the subcontractor

Explanation of Provision. Hospice programs may enter into arrangements with another certified hospice program to provide services. The provision for under arrangement services is limited to extraordinary or non-routine circumstances, such as unanticipated periods of staffing shortages. The originating hospice program continues to bear the legal responsibility for billing and maintaining quality of care.

Effective Date. Upon enactment.

Reason for Change. Hospice programs would be allowed to use personnel from other hospice programs to provide services to hospice patients. The program is given the flexibility so that a hospice program could continue to serve a patient if he or she was temporarily out of the area due to travel. Otherwise, the provision of the care to the patient might be delayed by the paperwork and requirements in starting up a new service at another agency. It is the intent of Congress that the originating hospice maintains control over the billing and quality of care.

III. Votes

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statements are made concerning the votes of the Committee on Ways and Means in its consideration of HR 2768.

MOTION TO REPORT THE BILL

HR 2768 was approved by voice vote with a quorum present

VOTES ON AMENDMENTS

Chairman Thomas' amendment in the nature of a substitute was approved by voice vote with a quorum present.

IV. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the following statement is made:

The Committee agrees with the estimate prepared by the Congressional Budget Office (CBO) which is included below.

B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the Committee bill results in no increase in federal direct spending.

C. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET OFFICE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives requiring a cost estimate prepared by the Congressional Budget Office (CBO), the following report prepared by CBO is provided.

{insert cost estimate from CBO}

V. OTHER MATTERS REQUIRED TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee reports that the need for this legislation was confirmed by the oversight hearings of the Subcommittee of Health. The hearings were as follows:

The Subcommittee on Health held a hearing on March 15, 2001 to examine how government can do its job better to ensure that beneficiaries are protected and that taxpayer dollars are used wisely and responsibly without placing undue burdens

CONGRESSIONAL BUDGET OFFICE
U.S. CONGRESS
WASHINGTON, DC 20515

Dan L. Crippen
Director

November 5, 2001

Honorable William M. Thomas
Chairman
Committee on Ways and Means
Washington, DC 20515

Dear Mr. Chairman:

The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2768, the Medicare Regulatory and Contracting Reform Act of 2001.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Alexis Ahlstrom and Niall Brennan, who can be reached at 226-9010. While the Ford House Office Building is closed, CBO analysts can be reached at 395-1260.

Sincerely,

Dan L. Crippen

Enclosure

cc: Honorable Charles B. Rangel
Ranking Democrat

IV C.

CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

November 5, 2001

H.R. 2768
Medicare Regulatory and Contracting Reform Act of 2001

As ordered reported by the House Committee on Ways and Means on October 11, 2001

SUMMARY

The Medicare Regulatory and Contracting Reform Act of 2001 would require the Centers for Medicare and Medicaid Services (CMS) to modify how Medicare regulations and policies are developed, communicated, and enforced, and would modify the procedures used to resolve disputes involving payment for services covered by Medicare. The bill would transfer certain administrative law judges from the Social Security Administration (SSA) to the Department of Health and Human Services (HHS). It would change the procedures by which Medicare makes contracts with entities, and would place new requirements on those entities. It would require the Secretary of HHS to conduct several demonstrations, and would require the completion of several studies and reports.

Assuming the appropriation of the necessary funds, CBO estimates that implementing H.R. 2768 would cost $41 million in 2002 and $548 million over the 2002-2006 period.

The procedural changes required by H.R. 2768 would affect spending for services covered by Medicare, which is direct spending. However, many of the bill's requirements codify existing practices, while the other requirements would cause minor increases or decreases in spending for covered services. CBO estimates that the changes in direct spending would be insignificant. Because the bill would affect direct spending, pay-as-you-go procedures would apply.

H.R. 2768 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). The requirement for public hospitals participating in the Medicare program to comply with the bloodborne pathogens standard promulgated by the Occupational Safety and Health Administration (OSHA) would have cost implications for state and local governments. However, those requirements would be conditions of participating in a voluntary federal program and thus would not be intergovernmental mandates as defined in UMRA. H.R. 2768 contains no private-sector mandates as defined in UMRA.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

For this estimate, CBO assumes that the legislation would be enacted this fall and that estimated amounts would be appropriated each year. The costs of this legislation fall within budget function 570 (Medicare).

BASIS OF ESTIMATE

Table 1 shows the estimated authorization levels and outlays for Medicare administrative expenses under current law and under H.R. 2768. Assuming appropriation of the estimated amounts, CBO estimates that enacting H.R. 2768 would cost $41 million in 2002 and $548 million over the 2002-2006 period.

TABLE 1. ESTIMATED BUDGETARY IMPACT OF H.R. 2768

	By Fiscal Year, in Millions of Dollars					
	2001	2002	2003	2004	2005	2006
SPENDING SUBJECT TO APPROPRIATION						
Spending for Medicare Administrative Costs Under Current Law						
Estimated Budget Authority[a]	3,352	3,500	3,646	3,797	3,955	4,118
Estimated Outlays	3,267	3,464	3,631	3,757	3,913	4,074
Proposed Changes						
Estimated Authorization Level	0	46	125	134	126	130
Estimated Outlays	0	41	116	133	128	129
Spending for Medicare Administrative Costs Under H.R. 2768						
Estimated Authorization Level	3,352	3,546	3,771	3,931	4,081	4,248
Estimated Outlays	3,267	3,505	3,747	3,890	4,041	4,203

a. Budget authority for 2001 is the amount appropriated for that year.

Contracting Reform. Under current law, CMS contracts with fiscal intermediaries and carriers to process and pay claims, to educate providers regarding Medicare billing policy, and for other purposes. This bill would change both the method by which CMS enters into contracts and the activities required of contractors. CBO expects that these provisions would increase the cost of administering contracts, the total amount CMS spends on contracts, and spending by contractors on the education of providers about Medicare billing practices. We estimate the cost of implementing these provisions would be $14 million in 2002 and $336 million during the 2002-2006 period.

H.R. 2768 would direct CMS to provide incentives to contractors who meet or exceed certain performance standards. Based on information furnished by CMS, we estimate that the incentive payments would total 3 percent of operating payments to contractors, or about $233 million over the 2002-2006 period.

H.R. 2768 would require CMS to competitively bid contracts with fiscal intermediaries and carriers at least every five years. CBO expects that an additional 3-5 FTEs at the GS-12 level would be needed throughout the period to write new competitively-bid contracts. The estimate assumes that about one-quarter of the contracts would be awarded to a nonincumbent bidder, and that it would cost about $2 million to transition between contractors. CBO estimates that implementing this provision would cost about $54 million over the 2002-2006 period.

In addition, the bill would direct the Medicare program to measure the payment error rates for individual contractors, which are believed to indicate how well providers understand proper Medicare billing procedures, with the intent of identifying contractors who have achieved high levels of provider education. This provision would expand current practice, which is to calculate a contractor-wide error rate. The bill would also expand the requirement for contractors to monitor the accuracy of information given to providers, and would limit the liability of contractors for payment errors. CBO estimates that complying with these provisions would cost about $27 million over the 2002-2006 period.

The bill also would instruct contractors to tailor their educational efforts toward providers with staffs of fewer than 26 people, or physicians with fewer than 11 staff members. The bill would authorize the appropriation of $10 million in 2003 and in 2004 to provide additional educational services. CBO estimates that 80 percent of the authorized amount would be spent in the current fiscal year and 20 percent the year after.

Appeals and Claims Payment Reform. H.R. 2768 would change the processes by which Medicare pays claims and adjudicates appeals by providers of payment denials. CBO estimates that implementing these provisions would cost $9 million in 2002 and $104 million over the 2002-2006 period.

Resubmission of Claims. Under current law, providers may pursue payment for claims initially submitted to contractors with errors and omissions either via resubmission of claims

in some instances or via the appeals process. H.R. 2768 would direct CMS to expand the instances in which providers may resubmit claims directly to contractors. CBO expects that this provision would lead to an increase in the number of incomplete claims submitted and a 1 percent increase in the number of claims processed. We estimate that processing those incomplete claims would increase costs by $5 million in 2002 and by $46 million over the 2002-2006 period.

Reliance on Guidance. H.R. 2768 would prohibit any sanction (including recoupment of overpayments) of a provider who relies on written guidance from contractors. CBO assumes this provision would increase the number of requests for written guidance by 50 percent. Under current law, contractors are required to respond to those requests. CBO estimates that the cost to contractors of issuing written responses to the additional requests, and the cost to CMS of oversight of those responses, would total less than $500,000 in 2002 and $29 million over the 2002-2006 period.

Standardization of Compliance Actions. The bill would also standardize existing policies regarding:

- Using random and non-random prepayment review,
- Using extrapolation after finding of overpayment,
- Enrolling providers and adjudicating appeals of enrollment denials,
- Communicating findings of overpayment to providers,
- Notifying providers regarding billing codes that the contractor suspects are being overused,
- Requiring providers to act within 45 days during the consent settlement process, and
- Collecting overpayments from providers.

CBO estimates that implementing those provisions would cost $28 million over the 2002-2006 period.

Appeals Reform. H.R. 2768 would modify the current appeals system. The bill would allow appellants to petition review boards for expedited access to judicial review outside of the Medicare review system. The bill would also require appellants to present all relevant evidence at the reconsideration level. These provisions are estimated to reduce administrative outlays by about $6 million over the 2002-2006 period because they are expected to reduce the caseload at the third and fourth level of appeals.

The bill would transfer certain administrative law judges (ALJs) from the Social Security Administration to the Department of Health and Human Services. CBO estimates that the costs of planning and implementing the transfer, and providing the ALJs with additional training on Medicare issues, would total $8 million over the 2002-2006 period.

These provisions would require CMS to make changes to current appeals and compliance systems but would not change the conditions under which Medicare would make payments to providers. Therefore, CBO estimates that these provisions would have no effect on direct spending.

Demonstrations and New Program Areas. H.R. 2768 would direct CMS to expand its programs to educate beneficiaries and providers. CBO estimates that implementing these provisions would cost $9 million in 2002 and $69 million during the 2002-2006 period.

The bill would create a demonstration project for the provision of technical services to small providers. Participating providers would receive education specifically related to their practice, as well as information about general Medicare billing and documentation requirements. Participants would contribute 25 percent of the costs of the technical assistance. The bill would authorize the appropriation of $1 million in 2003 and $6 million in 2004 for the demonstration.

The bill would also direct CMS to implement a three-year outreach demonstration in at least six locations throughout the United States. The program would involve the deployment of Medicare specialists to local Social Security Administration offices to provide beneficiaries assistance and advice regarding the Medicare program. CBO estimates that the costs of the demonstration, which would include the rental of office space, salaries for Medicare specialists, and travel, moving, and administrative expenses, would total $4 million over the 2002-2006 period.

H.R. 2768 would require CMS to develop two new ombudsman offices, for providers and beneficiaries, within the Medicare program. Each office would act as a liaison between either providers or beneficiaries and the agency. The offices would be responsible for offering advice and assistance to individuals regarding the program, as well as conveying the concerns of providers and beneficiaries to program officials. The bill would authorize such sums as may be necessary in 2002 and thereafter for these ombudsman offices. CBO estimates that the number of staff required to perform these functions would grow from 85 FTEs in 2002 to 155 FTEs in 2006. We estimate these ombudsman activities would cost $54 million over the 2002-2006 period.

H.R. 2768 would also require CMS to establish a Council for Technology and Innovation within CMS. The Secretary would appoint an Executive Coordinator for the council. CBO estimates that CMS would spend about $1 million a year to staff and operate the Council for Technology and Innovation.

Development of Policies, Procedures, and Time Lines. H.R. 2768 would require CMS to develop new policies, procedures, and time lines with regard to the issuance of regulations, documentation guidelines for evaluation and management services, and the Medicare Secondary Payer program. CBO estimates the cost of implementing these provisions would be $9 million in 2002 and $36 million during the 2002-2006 period.

Final Regulations. The bill would require CMS to create a time line for the publication of final regulations and limit publication of new regulations to once a month. There currently are 22 "interim final rules;" the bill would require CMS to make those rules final, and would require CMS to finalize all future regulations.

CBO estimates that it would cost about $9 million in 2002 to finalize existing interim final rules. We estimate that CMS would need to hire an additional 3 to 5 staff, at the GS-11 level or higher, and spend an additional $10 million through 2006 to comply with the requirement to finalize all future interim regulations and to produce the required reports.

Documentation Guidelines for Evaluation and Management (E&M) Services. H.R. 2768 would restrict CMS from implementing new documentation guidelines for evaluation and management services until several conditions have been met. Those conditions include:

- Establishing plans to improve the guidelines,
- Completing pilot projects to test modifications to the guidelines,
- Educating providers about the guidelines, and
- Consulting providers during the entire process of testing and establishing the guidelines.

CMS currently has E&M guidelines in place, and the bill would not require changes in those guidelines. CBO assumes that CMS will attempt to update those guidelines during the next few years, because both CMS and provider groups have expressed interest in doing so. The new procedural requirements would increase the cost of developing and implementing new E&M guidelines. Establishing new guidelines for E&M documentation would require the hiring of at least two FTEs for the administration of the pilot projects, for outreach to providers, and for consultation with providers. CBO further estimates that CMS would conduct at least three pilot projects, with each project costing around $1 million per year, and that the studies and reports required by these provisions would cost another $1 million.

Medicare Secondary Payer program. The Medicare Secondary Payer program requires providers and suppliers to collect insurance information from beneficiaries to determine whether Medicare will be the secondary payer on a claim. The bill would restrict Medicare from implementing special requirements for hospital-based laboratories that act as referral laboratories, with respect to gathering insurance information from patients, unless

independent laboratories are also required to collect such information. Under current policy, referral laboratories, which conduct tests without direct contact with patients, would have to begin gathering this information beginning in January 2002. CBO estimates that the costs of complying with this provision would be negligible.

Medicare Coverage Policies. H.R. 2768 would change the timing of CMS's national coverage decisions concerning certain new technologies. Upon request by an applicant, the Secretary would be required, to the extent feasible, to coordinate reviews of coverage decisions with the review for premarket approval conducted by the Food and Drug Administration. H.R. 2768 would require the Secretary to submit to the Congress a plan for achieving such coordination within six months. CBO estimates that establishing and operating the coordination process would cost $1 million in 2002 and $3 million over the 2002-2006 period.

PAY-AS-YOU-GO CONSIDERATIONS

The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. CBO estimates that the bill would not affect receipts and would have no significant effect on direct spending.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 2768 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act. The requirement for public hospitals participating in the Medicare program to comply with OSHA's bloodborne pathogens standard would have cost implications for state and local governments. The current OSHA standard applies to all private-sector employers with one or more employees, as well as to federal civilian employees. This bill would extend the requirement to all hospitals participating in the Medicare program, including state and local public hospitals. About half of the states currently have bloodborne pathogen standards that apply to these hospitals that are at least as stringent as the federal standard. Public hospitals in the remaining states could face additional costs as a result of the new requirement. Those costs, however, would result from participating in Medicare, a voluntary federal program, and thus would not be costs of an intergovernmental mandate as defined in UMRA.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

H.R. 2768 contains no private-sector mandates as defined in UMRA.

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on providers. Testimony at the hearing was presented by the Office of the Inspector General, patient and provider groups and experts on the Medicare program.

On September 25, 2001, the Subcommittee held a hearing on HR 2768, which includes provisions for facilitating access by beneficiaries and providers to information on the Medicare program, for improving the administration of the Medicare program and for reducing regulatory burden. The hearing included testimony from the Administration, the General Accounting Office, and health care providers.

B. SUMMARY OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In compliance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee states that the primary purpose of H.R. 2768 is to create a more collaborative, less confrontational relationship between providers and CMS.

C. CONSTITUTIONAL AUTHORITY STATEMENT

In compliance with clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, relating to constitutional Authority, the Committee states that the Committee's action in reporting the bill is derived from Article I of the Constitution, Section 8 ("The Congress shall have power ("The Congress shall have power to lay and collect taxes, duties, imposts and excises, to pay the debts and to provide for *** the general Welfare of the United States ***").

VI. CHANGES IN EXISTING LAWS MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):